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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/079,640	05/15/1998	HENRY DANIELL	922.6588P	8567

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/17/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/079,640

Applicant(s)

Daniell

Examiner

FOX

Group Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 3/28/02
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1, 3-213 is/are pending in the application.
- Of the above claim(s) 1, 85, 97-106, 108-117, 120, 121, 123-163, 170, 177-188, 200-213 is/are withdrawn from consideration.
- ☒ Claim(s) 4-84, 86-96, 107, 118, 119, 122, 168, 169, 172-176, 189 is/are allowed. and 194-195
- ☒ Claim(s) 3, 171, 190-193 and 196-199 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The application should be reviewed for errors. Errors appear, for example, in claim 190, line 10, where “of” after “competent” should be deleted.

The indication in the last Office action on page 7 (and on the Office Action Summary) that claim 192 was merely objected to was a typographical error. Claim 172 was objected to. Claim 192 was clearly rejected, as set forth on pages 3-6 of the last Office action. The error is regretted.

The amendments of 28 March 2002 have obviated the errors and rejections under 35USC 112, second paragraph, of record.

Claims 3, 171 and 190-192 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-23, 25-29, 31 and 34 of U.S. Patent No. 5,932,479. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons presented in the last office action.

Claims 3, 171 and 190-192 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 119-120, 124, 132, 140-142, 153-157, 166-167 and 188 of copending Application No. 08/972,901. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons presented in the last office action.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Applicant's intent to file a Terminal Disclaimer is noted. The rejections will be maintained until receipt of a properly executed Terminal Disclaimer.

Claim 198 (newly amended) is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 198 is indefinite in its recitation of "into the chloroplast genome of the target plant" in the third line from the bottom, which is redundant in view of the amendment to insert the particular targeted region in the last line of the claim. Furthermore, the claim is indefinite in its recitation of "in a" in the penultimate line, which is awkward and should be replaced with --into a--.

Claims 3, 171, 190-193 and 196-199 (newly amended) are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no basis in the specification for the newly added phrase "transcriptionally active polycistronic spacer region" in amended claims 190-193 and 196-199 and dependents.

Accordingly, this phrase constitutes NEW MATTER.

Claims 3, 171, 190-192 and 196-199 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the intergenic spacer 2 region between the trnA and trnI genes of the chloroplast genome of higher plants, does

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not reasonably provide enablement for claims broadly drawn to the use of any intergenic spacer region. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action on page 4.

Claims 190-191 and 196-197 remain, and amended claims 192-193, 198 and 199 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the intergenic spacer 2 region between the trnA and trnI genes of the chloroplast genome of higher plants for the homologous recombination-mediated insertion of heterologous DNA into the intergenic spacer 2 region of the chloroplast genome of target higher plants, does not reasonably provide enablement for the insertion of heterologous DNA into any “transcriptionally active polycistronic spacer region” of the chloroplast genome of a multitude of target higher plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action for claims 190-191 and 196-197.

Claim 192 remains rejected under 35 U.S.C. 102(b) as being anticipated by Zoubenko et al, as stated in the last office action.

Claim 192 remains rejected under 35 U.S.C. 102(b) as being anticipated by Staub et al (1993), as stated in the last office action.

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The rejection of claims 3, 171 and 190-192 under 35 USC 102(b) as being anticipated by Staub et al (1995) in light of Sidorov et al (1999) has been withdrawn in view of Applicant's amendment to recite the insertion of heterologous DNA into a polycistronic spacer region. However, as noted above, this amendment constitutes NEW MATTER. Deletion of the phrase will result in reinstatement of the art rejection.

Claims 4-84, 86-96, 107, 118-119, 122, 168-169, 172-176, 189, and 193-199 remain free of the prior art, as stated in the last office action.

Claims 4-84, 86-96, 107, 118-119, 122, 168-169, 172-176, 189 and 194-195 are allowed.

Applicant's arguments filed 28 March 2002 have been fully considered but they are not persuasive, insofar as they pertain to the rejections above.

Applicant urges that the enablement rejections are improper, given the instructions in the specification for the identification of other conserved spacer regions and the disclosure of chloroplast genome sequences by other workers. The Examiner maintains that it is unclear whether other such polycistronic transcriptionally active spacer regions exist in other chloroplast genomes. No particular region of the exemplified spacer region has been identified which is conserved among its class, which could be used as a probe. In the absence of such information, the skilled artisan would be forced to resort to an infinite number of trial-and-error experiments in an effort to identify even one other possible successful event. Such experimentation is undue. Applicant is also directed to Maier et al appended to the amendment of 28 March 2002, which demonstrates that chloroplast genomic regions are not all conserved among all higher plants (see,

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e.g., page 13 of the amendment of 28 March 2002). Finally, the Examiner has provided evidence in the form of scientific reasoning and literature citations to support his position. See In re Marzocchi & Horton, 169 USPQ 367 (at page 370, column 1, top paragraph), (CCPA 1971).

Applicant urges that the art rejection over Zoubenko et al is improper, given the teaching by that reference that the trnv-rps12/7 spacer region is unique to the tobacco chloroplast genome, rather than “conserved in all higher plants” as claimed. The Examiner responds that the reference merely teaches that two ORFs within that spacer, namely ORF131 and ORF70B, are unique to tobacco. The reference does not teach that other sequences within that spacer region are unique to tobacco, wherein said other regions could be used to provide the flanking regions of the claimed construct. The claims are not limited to a spacer region which comprises both ORF131 and ORF70B from tobacco.

Applicant urges that the art rejection over Staub et al (1993) is improper, given the failure of the reference to teach flanking sequences from a target plant species different from the species into which the vector was inserted. The Examiner maintains that the rejected claim is a product claim, wherein the identity of the target plant species is merely an intended use, as stated previously. The vector taught by Staub et al (1993) could be used to transform a target plant other than tobacco. Intended use is not given patentable weight in product claims.

Regarding the withdrawn rejection under 35 USC 102, the Examiner notes that Maier et al was not relied upon in the decision to withdraw. Although Maier et al teach that the order of the rbcL and accD genes in maize is not typical, they do not teach that all of the sequences flanking

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the *rbcL* gene in maize are unique to that species. Thus, other portions of the spacer region could have been used in a vector to transform other higher plants. The claims are not limited to a particular spacer which comprises both the *rbcL* and the *accD* genes.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

June 14, 2002

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 1638

